

PROGESTIN-ONLY ORAL CONTRACEPTION

I. INTRODUCTION

Progestin-only contraceptives (POPs), contain a progestin but no estrogen. This pill is often referred to as “the minipill.” The primary mechanism of action is cervical mucus thickening and thinning of the endometrial lining making it not receptive to ovum implantation. Additionally, inhibition of ovulation can occur but not consistently.

Perfect use failure rate in the first year: 0.3%

Typical use failure rate in the first year: 9%

Typical use failure is directly related to patient compliance with use. Studies show that teens have a difficult time complying with daily use of oral contraceptives (OCs), therefore, alternative methods of contraception should be encouraged.

Patients using POP should receive counseling about and, as needed, prescriptions for emergency contraception (EC).

II. ORAL CONTRACEPTIVE PILL TYPES, FORMULATIONS, AND PILL-USE PATTERNS

1. In the US, the POPs are composed of norethindrone 0.35mg tablets. The pills are dispensed in a 28 day package that has no pill free or non-hormonal week.
2. The progestin-only contraceptive pill is taken daily continuously, every day without interruption. Because POPs have a short duration of action (20 hours) and a short half-life it is essential that they are taken at the exact same time every day.

III. BENEFITS AND DISADVANTAGES OF POPs

- A. Progestin-only contraceptive pill (POPs) benefits:
- Estrogen-free, and therefore, useful for clients unable to tolerate the estrogen effects of combined oral contraceptives or who have contraindications against taking an estrogen-containing contraceptive. Of note, many of the contraindications listed on the package insert were established for estrogen-progestin pills and then extrapolated to progestin-only methods because clinical trials have not evaluated the safety of progestin only forms of contraception in women with contraindications to estrogen.
1. Can be taken during lactation.
 2. Appears to have no harmful effect on blood pressure or on coagulation.
- B. Progestin-only contraceptive pills (POPs) disadvantages:
1. Irregular menstruation.

2. Requirement for more exact timing of daily dosage than with the combined pills. If the minipill is taken 3 or more hours later than the usual time, a back-up method should be used for at least 48 hours.

IV. CLIENT SELECTION

A. Indications:

1. POPs may be provided when contraindications do not exist.
2. May be a good choice for clients that cannot use/have medical contraindications to estrogen-containing method.

B. Contraindications:

Of note, many of the contraindications listed on the package insert were established for estrogen-progestin pills and then extrapolated to progestin-only methods because clinical trials have not evaluated the safety of progestin only forms of contraception in women with contraindications to estrogen.

(USMEC 3-- Risks outweigh advantages for method use. USMEC 4--

Unacceptable risk for method use)

1. Current breast cancer (USMEC 4)
2. Past breast cancer and no evidence of disease in 5 yrs. (USMEC 3)
3. History of ischemic heart disease or stroke (USMEC 3 for continuation not initiation)
4. Cirrhosis (severe-decompensated) (USMEC 3)
5. Liver tumors – adenoma or malignant (USMEC 3)
6. Systemic Lupus Erythematosus –positive (or unknown) antiphospholipid antibodies (USMEC 3)
7. History of Bariatric Surgery- malabsorption procedure only (USMEC 3)
8. Migraines with aura (USMEC 3 for continuation not initiation)
9. Use of medications known to increase liver enzyme metabolism and thus may decrease contraceptive effectiveness. (USMEC 3):
 - a. **Anti Epilepsy Drugs (AEDs)** – may also be used to treat certain psychiatric illnesses, headaches, chronic pain and other conditions (USMEC 3):
 - i. Carbamazepine (Tegretol®)
 - ii. Oxcarbazepine (Trileptal®)
 - iii. Phenobarbital
 - iv. Phenytoin (Dilantin®)
 - v. Primidone (Mysoline®)
 - vi. Toprimate (Topamax®) – mild decrease
 - b. **Antiretroviral (ARV) therapy**
 - i. Fosamprenavir
 - c. **Anti-Mycobacterials**
 - i. Rifampin
 - ii. Rifampicin
 - iii. Rifamate

V. INITIATION OF PROGESTIN-ONLY ORAL CONTRACEPTIVE PILLS

- ##### A. Patients starting on OCPs are not required to have a pelvic examination, and access to contraception should not be delayed while waiting for cervical cancer

- screening. For women at risk, STI testing is encouraged, but can be performed through urine testing.
- B. QuickStart: QuickStart protocols are highly encouraged when a patient is starting (or restarting) oral contraceptive pills (COC or POP). Quickstart improves compliance with starting the second month of OCP, and may decrease risk of unintended pregnancy.
 - 1. Take the first pill of the pack on the day of the visit.
 - 2. A back-up method of contraception is recommended for 7 days.
 - 3. If the client is in need of emergency contraception, she should take both tablets of Plan B® at once on the visit day and start her pills no later than the next day.
 - 4. Her next menses may be delayed until she completes her first cycle of pills.
 - 5. Quick start does not increase irregular spotting or bleeding.
 - 6. The client should check a pregnancy test if she has not seen a normal menses within 4 weeks of starting OCP.
 - C. First-Day Start:
 - 1. Take the first pill of the pack on the first day of the menses.
 - 2. No back-up contraception is needed.
 - D. Sunday Start:
 - 1. Take the first pill of the pack on the Sunday after the first day of the menses.
 - 2. A back-up method of contraception is recommended for 7 days.
 - 3. Sunday starts usually result in no periods on the weekends.
 - E. Postpartum Start:
 - 1. Can be started in both breastfeeding and non-breastfeeding women at any time
 - 2. Do not wait for the first menses to start contraception, as most women will ovulate before their first menstrual period.
 - F. For new POP starts, dispense a 3-month supply. Also provide the client with a prescription for a year-supply of the POP, so access to contraception is not limited by requiring the client to return to clinic. Clients may return for additional pills to be dispensed as needed.
 - G. New users should return in 1-3 months to assess compliance and satisfaction.
 - H. TIMING OF PILLS
 - 1. It is essential that the pill be taken at the same time each day.
 - 2. If the POP is taken more than 3 hours late or missed on any day the patient should abstain or use a back form of birth control for at least 3 days.
 - 3. Once noticed the client should take the missed/late pill as soon as possible even if this means 2 pills are taken on the same day.
 - 4. If more than two pills are missed/delayed, emergency contraception can be considered and a back up form of birth control should be used for 7 days. A pregnancy test should be taken in 14 days to rule out pregnancy if unprotected intercourse is performed or emergency contraception was taken.

V. CLIENT EDUCATION/ INFORMED CONSENT

All clients being provided an oral contraceptive should receive the following:

- A. Information/counseling regarding all contraceptive options available
- B. Information specific to oral contraceptive method of choice including effectiveness, benefits, risks, use, danger signs, potential side effects, complications and discontinuation issues (Appendix A and B).

- C. Prescription/counseling about emergency contraception, and, for teens, a prescription with multiple refills.
- D. Instruction that contraceptive effectiveness may be reduced with co-administration of other drugs (See Client Selection criteria).
- E. Instruction on missed pills - Instruct the client to follow these recommendations. Additionally, for some situations the use of emergency contraceptive pills may be considered (see above).
- F. Information that oral contraceptives do not offer protection against STIs/HIV, the routine use of condoms should be encouraged to decrease STI risk.
- G. Instruction/counseling on importance of reading the Patient Package Insert (PPI)
- H. Written and verbal instruction on method use (may use Package Insert)
- I. Emergency, 24-hour telephone number and location where emergency services can be obtained.
- J. Clinic access information.

VI. FOLLOW-UP

- A. The client should return in 1-3 months for evaluation for oral contraception continuation. The client should be evaluated for side effects, satisfaction and compliance
- B. Serious side effects that may warrant immediate consultation and discontinuation include:
 - 1. Sharp chest pain, coughing up blood, or sudden shortness of breath.
 - 2. Pain in calf or leg.
 - 3. Crushing chest pain or tightness in the chest.
 - 4. Sudden severe headache or vomiting, dizziness or fainting, disturbances of vision or speech, weakness or numbness in an arm or leg.
 - 5. Sudden partial or complete loss of vision.
 - 6. Breast masses suspicious for potential malignancy.
 - 7. Severe abdominal pain or tenderness.
 - 8. Severe problems with sleeping, weakness, lack of energy, fatigue, or change in mood.
 - 9. Jaundice.
 - 10. Swelling of the fingers or ankles.

VII. MANAGEMENT OF SIDE EFFECTS AND COMPLICATIONS

- A. Symptoms such as headache, nausea, vomiting, mastalgia, weight gain, irritability, fatigue, and mood changes are usually transient.
- B. Breakthrough bleeding is common with POPs. In the first few months should be managed by encouragement and reassurance. If it occurs after many months of use and bothersome to the patient then changing to another form of contraception may be appropriate after evaluation.
- C. In addition to signs or symptoms of DVT or other clotting disorders or liver dysfunction, sometimes discontinuation of oral contraception may be necessary for other reasons. Reasons for stopping oral contraceptives:
 - 1. With evidence of severe clinical depression, refer the client for psychiatric evaluation. If depression is felt to be worsened by the oral contraceptives,

- you may consider stopping the method and initiating a non-hormonal method immediately. For mild mood changes a different formulation may be offered.
2. Any client desiring to become pregnant may be advised to continue use of OCP until pregnancy is desired. Most women can become pregnant within a year of stopping OCP, similar to women who are not using hormonal contraception. The client should receive preconception counseling and be instructed in the importance of taking a daily multivitamin preparation containing 0.4 mg of folic acid.
 3. Any client with post-pill amenorrhea of more than 6 months should be referred for evaluation.

VIII. DOCUMENTATION

- A. Order must be written in medical record initially, annually, and upon method change.
- B. Oral contraceptives dispensed must be documented in the medical record and/or computer system.
- C. All education/counseling must be documented.

REFERENCES

1. Medical Eligibility Criteria for Contraceptive Use. MMWR / July 29, 2016 / Vol. 65 / No. 3
2. Hatcher, R., et. Al. Contraceptive Technology. 20th Edition, 2011.
3. Westhoff, C., Heartwell, S., Edwards, S., et al. "Initiation of Oral Contraceptives: a Randomized Trial of Quick Start versus Conventional Start" *Obstet Gynecol.* 109 1270-1276 2007

APPENDIX A

POSSIBLE HEALTH BENEFITS OF Progestin Only Oral Contraception

1. Lower risk of pelvic inflammatory disease
2. Lower risk of endometrial cancer
3. Decrease in frequency of ectopic pregnancy
4. A protective effect against osteoporosis especially in breastfeeding women
5. Decreased number of sickle cell crises

APPENDIX B

POSSIBLE HEALTH RISKS OF Progestin Only Oral Contraception

1. Unscheduled bleeding and menstrual cycle
2. Follicular cysts
3. Liver disease exacerbation